REMARKS

The Office Action mailed January 29, 2004 has been received and reviewed. Claims 1 through 20 are noted as pending in the Office Action. Applicants have amended claims 1, 2, 7, 8, 10 and 14, canceled claims 16 through 20, and added new claims 21 to 24. Reconsideration is respectfully requested.

35 U.S.C. § 112 First Paragraph Rejections

Claims 1 through 7 were rejected in the Office Action as assertedly lacking enablement under the first paragraph of 35 U.S.C. § 112. While applicants disagree, independent claim 1 has been amended to expedite prosecution, and it is respectfully submitted that amended claim 1, with claims 2 through 7 dependent therefrom, is enabled.

The Office Action stated that "the specification, while being enabling for an *in vitro* method for delivering genetic material to a target cell, does not reasonably provide enablement for an *in vivo* method for delivering genetic material to a target cell." (Office Action at page 2). Amended claim 1 is directed to a "method for delivering genetic material to a target cell ***in vitro***" and includes the elements of "delivering said gene delivery vehicle complex to the target cell ***in vitro***" (emphasis added). Independent claim 1 is thus drawn to subject matter noted as enabled in the Office Action.

35 U.S.C. § 112 Second Paragraph Rejections

Claims 1 through 7 were rejected in the Office Action as assertedly being incomplete for omitting essential steps. The Office Action states that the omitted steps are "the expression of the delivered nucleic acid in the target cell." (Office Action at page 6). Applicants respectfully traverse this rejection.

As amended, claim 1 is directed to a "method for delivering genetic material to a target cell *in vitro*." The method is merely directed to the *in vitro* delivery of the genetic material to a target cell, not to both delivery and expression of the delivered genetic material. For example, in a pre-clinical setting, the method could be used to identify desired targeting vehicles, without an attempt to express the genetic material. (See paragraph [0045] of the as-filed application).

Accordingly, it is respectfully requested that the rejection be withdrawn and amended claim 1, with claims 2 through 7 dependent therefrom, be allowed.

Claims 2, 7 and 14 were rejected in the Office Action as assertedly being indefinite under the second paragraph of 35 U.S.C. § 112. The language "wherein said first member of the specific binding pair is configured without a specific affinity for the target molecule" in claim 2 was asserted to be confusing. (Office Action at page 7). Claim 2 has been amended to recite "the specific binding pair has no specific affinity for said target molecule," and applicants respectfully submit that amended claim 2 is definite.

The language "wherein said capsid or envelope is configured to be incapable of binding to the target cell" in claim 7, was asserted to be unclear (Office Action at page 7). Applicants amended claim 7 to recite "wherein said capsid or envelope is incapable of binding to the target cell" and submit that amended claim 7 is definite.

Claim 14 was asserted to be indefinite with respect to the language "derived from," as the "metes and bounds of the virus recited in the claims is not clearly set forth" (Office Action at page 7). Claim 14 has been amended to recite "wherein said virus is derived from a virus selected from the group consisting of adenoviruses, adeno-associated viruses, and retroviruses **by altering the capsid or envelope of said virus**" (emphases added). Applicants respectfully submit that amended claim 14 is definite.

35 U.S.C. § 102(b) Anticipation Rejections

Anticipation Rejection Based on Curiel et al. (1994).

Claims 1 through 20 were rejected in the Office Action as assertedly anticipated by Curiel et al. (1994). Claims 16 through 20 have been canceled, rendering this rejection moot as to them. With respect to the remaining claims, applicants respectfully traverse this rejection, as hereinafter set forth.

A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Brothers v. Union Oil Co. of California*, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). The identical invention

must be shown in as complete detail as is contained in the claim. *Richardson v. Suzuki Motor Co.*, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989).

The Office Action states:

> Curiel et al. (1994) disclose a gene delivery vehicle comprising a biotinylated adenovirus. Plasmid DNA encoding ß-galactosidase is coupled to the **exterior** of the viral particles by steptavidin-polylysine complexes. They, the biotinylated adenovirus coupled to the plasmid DNA via the steptavidin-polylysine complex is the gene delivery vehicle defined in Claim 1. (Office Action at page 7, emphasis added).

This statement is supported by the Abstract of Curiel et al. (1994), which states that "Plasmid DNA is coupled to the exterior of viral particles by streptavidin-polylysine chimeric proteins." (Curiel et al. (1994) page 577).

In contrast, independent claim 1 includes the elements of "preparing a gene delivery vehicle comprising an expressible nucleic acid molecule encoding a recombinant gene of interest, **a virus including a capsid or envelope surrounding said expressible nucleic acid molecule**, and a first member of a specific binding pair, said first member of the specific binding pair expressed on an exterior of said capsid or envelope and said first member of the specific binding pair not being a viral antigen naturally expressed on said delivery vehicle" (emphasis added). Similarly, independent claim 8 includes the elements of "a gene delivery vehicle, said gene delivery vehicle comprising an expressible nucleic acid molecule encoding a recombinant gene of interest, **a virus including a capsid or envelope surrounding said expressible nucleic acid molecule**, and a first member of a specific binding pair" (emphasis added).

Accordingly, each of independent claims 1 and 8 should patentably define over Curiel et al. (1994) as should claims 2 through7 and 9 through 15 respectively dependent therefrom. It is requested the rejection be withdrawn.

Anticipation Rejection Based on Roux et al. (1989).

Claims 1 through 20 were rejected in the Office Action as assertedly anticipated by Roux et al. (1989). Claims 16 through 20 have been canceled, rendering this rejection moot as to them.

With respect to the remaining claims, applicants respectfully submit that amended independent claims 1 through 8 define over Roux et al.

As explained in the Roux et al. Abstract, the cited reference discloses a procedure allowing *in vitro* cell targeting by retroviruses, where "[b]iotinylated antibodies **against the viral envelope protein** on one side and against specific cell membrane markers on the other side" were used.

By contrast, amended claim 1 now recites the elements of "preparing a gene delivery vehicle comprising an expressible nucleic acid molecule encoding a recombinant gene of interest, a virus including a capsid or envelope surrounding said expressible nucleic acid molecule, and a first member of a specific binding pair, said first member of the specific binding pair expressed on an exterior of said capsid or envelope and **said first member of the specific binding pair not being a viral antigen naturally expressed on said delivery vehicle.**" Similarly, amended claim 8 includes the elements of "said first member of the specific binding pair expressed on an exterior of said capsid or envelope and **said first member of the specific binding pair not being a viral antigen naturally expressed on said delivery vehicle**." Support for the amended claims may be found at paragraphs [0019] and [0023] of the as-filed specification. As each of these independent claims contains elements not disclosed in Roux et al., it is respectfully submitted that they define thereover, as do the claims dependent therefrom.

Anticipation Rejection Based on Russell et al. (1993).

Claims 1 through 20 were rejected in the Office Action as assertedly anticipated by Russell al. (1993). Claims 16 through 20 have been canceled, rendering this rejection moot as to them. With respect to the remaining claims, applicants respectfully traverse this rejection.

Independent claim 1 includes the elements of "coupling **a bispecific conjugate** to said first member of the specific binding pair to form a gene delivery vehicle complex, **said bispecific conjugate comprising a second member of the specific binding pair covalently coupled to a targeting moiety**, said targeting moiety capable of binding to a target molecule associated with a surface of the target cell" (emphasis added). Similarly, independent clam 8 includes the elements of "**a bispecific conjugate** for coupling to said first member of the specific binding pair, **said**

bispecific conjugate comprising a second member of the specific binding pair covalently coupled to a targeting moiety, said targeting moiety capable of binding to a target molecule associated with a surface of the target cell" (emphasis added). In contrast, Russell et al. discloses the direct incorporation of an antibody fragment into a retroviral envelope, not a bispecific conjugate. (*See*, Russell, et al., Abstract). Accordingly, independent claims 1 and 8, with the remaining claims dependent therefrom define over Russell et al.

CONCLUSION

All pending claims are believed to be in condition for allowance, and an early notice thereof is respectfully solicited. Should the Office determine that additional issues remain which might be resolved by a telephone conference, the Examiner is respectfully invited to contact applicants' attorney.

Respectfully submitted,

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